13-1418

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

GILEAD SCIENCES, INC., HOFFMANN-LA ROCHE, INC.,
F. HOFFMANN-LA ROCHE, LTD., and GENENTECH, INC.,

Plaintiffs-Appellees,

—v.—

NATCO PHARMA LIMITED and NATCO PHARMA, INC.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
JUDGE SUSAN D. WIGENTON
11-CV-1455(L), 11-CV-4969(CON)

BRIEF FOR PLAINTIFFS-APPELLEES

LEORA BEN-AMI
PATRICIA A. CARSON
BENJAMIN A. LASKY
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
(212) 446-4800

Counsel for Plaintiffs-Appellees

September 17, 2013

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 26.1, 28(a)(1), and 47.4, counsel for Plaintiffs-Appellees certify the following:

1. The full names of every party represented by me are:

   Gilead Sciences, Inc.
   Hoffmann-La Roche Inc.
   F. Hoffmann-La Roche Ltd.
   Genentech, Inc.

2. The name of the real party in interest is: *N/A*

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

   No corporation or publicly held company is the parent or owns 10 percent or more of the stock of Gilead Sciences, Inc.

   Hoffmann-La Roche Inc.'s ultimate parent, Roche Holding Ltd., is publicly traded on the Swiss Stock Exchange. Upon information and belief, more than 10 percent of Roche Holding Ltd.'s voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation. Apart from Roche Holding Ltd. (and indirectly, Novartis AG), there is no publicly held company with a 10 percent or greater ownership of Hoffmann-La Roche, Inc.

   F. Hoffmann-La Roche Ltd. is a wholly-owned subsidiary of Roche Holding Ltd., a publicly held Swiss corporation. Upon information and belief, more than 10 percent of Roche Holding Ltd.'s voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

   The parent companies of Genentech, Inc. are: Roche Holdings, Inc., Roche Finance Ltd. and Roche Holding Ltd. Roche Holding Ltd. is a publicly traded company indirectly owning 10% or more of Genentech, Inc.'s stock. Upon information and belief, more than 10 percent of Roche Holding Ltd.'s voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by me in the trial court or are expected to appear in this Court are:

Kirkland & Ellis LLP
Leora Ben-Ami
Patricia A. Carson
Benjamin A. Lasky

Connell Foley LLP
Liza M. Walsh
Rukhsanah L. Lighari

September 17, 2013 /s/ Patricia A. Carson

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

STATEMENT OF RELATED CASES

Counsel for Plaintiffs-Appellees are unaware of any related cases currently pending before this Court or any other court that will directly affect or be affected by this Court's decision in this appeal.

STATEMENT OF JURISDICTION

Plaintiffs-Appellees agree that jurisdiction was proper in the district court under 28 U.S.C. § 1331 and 1338(a), is proper in this Court under 28 U.S.C. § 1295(a)(1), and was timely invoked by Defendants-Appellants' May 20, 2013 notice of appeal from the district court's December 21, 2012 summary judgment opinion and order, and May 9, 2013 judgment (certified as final under 54(b)).

COUNTER-STATEMENT OF THE ISSUES

Whether the district court correctly ruled—in accordance with almost a century-and-a-half of precedent—that a later-issued, earlier-expiring patent cannot be used as an obviousness-type double patenting reference to invalidate an earlier-issued, later-expiring patent.

COUNTER-STATEMENT OF THE CASE

This is a patent infringement action brought by Plaintiffs-Appellees Gilead Sciences, Inc. ("Gilead Sciences"), Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd. (collectively, "Hoffmann-La Roche") and Genentech, Inc. ("Genentech")[1] against Defendants-Appellants Natco Pharma Limited and Natco Pharma Inc. (collectively, "Natco") for infringement of U.S. Patent No. 5,763,483 ("the '483 patent").

Gilead Sciences owns the '483 patent, titled "Carbocyclic Compounds," which claims, *inter alia*, compositions comprising the neuraminidase inhibitor oseltamivir, and methods for using those compositions to treat influenza. Hoffmann-La Roche and Genentech are exclusive licensees of the '483 patent. Hoffmann La-Roche holds New Drug Application ("NDA") No. 21-087 on dosage forms containing oseltamivir phosphate, marketed as TAMIFLU®, for treatment of influenza. The '483 patent is listed in the U.S. Food and Drug Administration ("FDA") publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as "the Orange Book") in connection with NDA No. 21-087.

In February 2011, Natco provided notice that it had filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market generic copies

[1] Plaintiffs-Appellees are referred to collectively as "Gilead."

of certain TAMIFLU® dosage forms before the expiry of the '483 patent, together with a "Paragraph IV" certification with respect to the '483 patent. By doing so, Natco infringed the '483 patent pursuant to 35 U.S.C. § 271(e)(2). Gilead therefore commenced an action in the United States District Court for the District of New Jersey—No. 2:11-cv-01455—which was assigned to District Judge Susan D. Wigenton. Subsequently, in August 2011, Natco provided notice that it had submitted an amendment to its ANDA seeking approval to market additional TAMIFLU® dosage forms before the expiry of the '483 patent, again providing a "Paragraph IV" certification with respect to the '483 patent, and thereby again infringing the '483 patent under 35 U.S.C. § 271(e)(2). Gilead therefore commenced a second action in the New Jersey district court—No. 2:11-cv-04969—which also was assigned to Judge Wigenton. The two cases were consolidated by agreement of the parties on September 9, 2011.

In the consolidated action, Natco contested infringement of claims 1 and 4-7 of the '483 patent, but did not contest infringement of claims 2 and 3. And, Natco asserted only a single invalidity argument with respect to all claims of the '483 patent—obviousness-type double patenting over the claims of commonly-owned U.S. Patent No. 5,952,375 ("the '375 patent").

On June 1, 2012, Gilead moved for summary judgment on Natco's obviousness-type double patenting defense on the ground that the later-issued,

earlier-expiring ’375 patent may not be used as a double patenting reference against the earlier-issued, later-expiring ’483 patent-in-suit as a matter of law. On June 29, 2012, Natco submitted its opposition brief together with a cross-motion for partial summary judgment that the ’375 patent may serve as a double-patenting reference against the ’483 patent. Gilead submitted its reply brief in support of its summary judgment motion, and opposition to Natco’s cross-motion, on July 27, 2012, and Natco submitted its reply brief in support of its cross-motion on August 23, 2012.

On December 12, 2012, the district court issued an opinion and order granting Gilead’s motion for summary judgment of no obviousness-type double patenting, and denying Natco’s cross-motion. Subsequently, on May 9, 2013, the district court, pursuant to the parties’ stipulation, entered final judgment that Natco infringed claims 2 and 3 of the ’483 patent, and that claims 1-7 of the ’483 patent are valid, staying resolution of Gilead’s remaining infringement allegations. The court certified the judgment for immediate appeal under Federal Rule of Civil Procedure 54(b). Natco filed a notice of appeal on May 20, 2013.

COUNTER-STATEMENT OF FACTS

I. While Investigating Novel Neuraminidase Inhibitors for Treatment of Influenza, Gilead Sciences Researchers Discovered Oseltamivir, the Active Ingredient in TAMIFLU®, in Mid-1995.

In the early 1990s, the treatment options for influenza were limited. A product known as SYMMETREL® (amantadine) was available, but could only treat one type of influenza. (A109.) A more broad-spectrum agent, RELENZA® (zanamivir) was just entering clinical development, but once approved in 1999, could only be administered by inhalation—a disadvantage over oral administration resulting in patient discomfort and non-compliance. (*Id.*)

Researchers at Gilead Sciences recognized a pressing need for a potent and safe anti-influenza agent that could be administered orally and used to treat a wide range of influenza strains. (*Id.*) Those researchers, led by Dr. Choung Kim, began a program aimed at finding a new agent that could fill that need. (*Id.*; A507.)

Dr. Kim's research initially focused on a broad genus of carbocyclic compounds, which showed promise as neuraminidase inhibitors. (A109; A507.)[2] Eventually, after synthesizing and testing hundreds of candidate compounds, Dr. Kim and his team discovered oseltamivir in mid-1995. (A109.) Oseltamivir was a breakthrough discovery—studies showed that it is a highly potent, uniquely safe,

[2] Neuraminidase is an enzyme that has been implicated in the pathogenicity of the influenza virus, and is thought to assist the movement of the virus through the mucus of the respiratory tract. (A32, 1:22-26.) Neuraminidase is therefore a target of certain anti-influenza drugs. (*Id.*)

orally bioavailable compound that is extremely effective against a range of influenza strains. (*Id.*; A507)

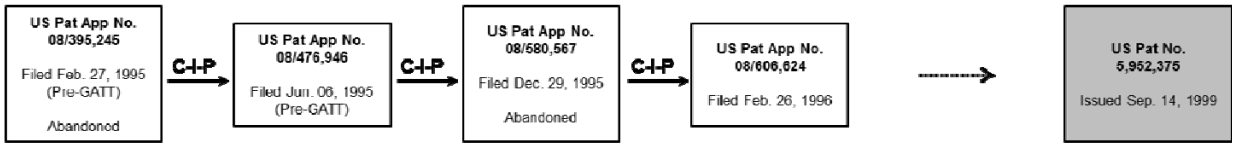
After further years of effort and hundreds of millions of dollars of investment, the phosphate salt of oseltamivir was approved by the FDA in June 1999 for the treatment of influenza, pursuant to NDA No. 21-087 held by Hoffmann-La Roche Inc. (A109; A138-39; A507.) Oseltamivir phosphate is currently marketed as TAMIFLU® and is one of the most successful influenza treatments on the market. (*Id.*)

II. Gilead Sciences' Pioneering Work was Reflected in a Series of Patent Applications Filed in 1995 and 1996, Resulting in the First-Issued '483 Patent-In-Suit, Followed a Year Later by the '375 Patent.

Figure 1 below illustrates the prosecution of the patents at issue here. The applications that ultimately issued as the '375 patent are shown in 1(a) and the applications that ultimately issued as the '483 patent are shown in 1(b).

Figure 1

(a) The '375 Patent



(b) The '483 Patent

As depicted in Figure 1(a), on February 27, 1995, Gilead Sciences filed with the United States Patent and Trademark Office ("PTO") the first of a series of patent applications related to its neuraminidase inhibitor research—no. 08/395,245 ("the '245 application"). (A358-65; A508; A529.) That application provided the first disclosure of Gilead Sciences' target genus of carbocyclic compounds, and identified a number of exemplary species compounds.

In the months that followed, as its research continued and additional promising compounds were identified, Gilead Sciences diligently disclosed these new discoveries in a series of continuation-in-part ("CIP") applications: (1) no. 08/476,946 ("the '946 application"), filed June 6, 1995; (2) no. 08/580,567 ("the '567 application"), filed December 29, 1995; and (3) no. 08/606,624 ("the '624 application"), filed February 26, 1996. (A151; A368-82; 508-09; 529.) Each of these CIP applications added scientific detail regarding the newly discovered target compounds and, in some cases, named additional inventors. (A509.)[3]

Meanwhile, as depicted in Figure 1(b), recognizing the particular promise and unexpected advantages of oseltamivir, Gilead Sciences filed U.S. provisional application no. 60/009,306 ("the '306 provisional") describing that compound on

[3] A CIP application "partly continues subject matter disclosed in a prior application, but it adds new subject matter not disclosed in the prior application." *Univ. of W. Va. Bd. of Trustees v. VanVoorhies*, 278 F.3d 1288, 1297 (Fed. Cir. 2002).

December 29, 1995. (A30; A511; A529.) In order to invoke the provisional procedure, which was specifically instituted by Congress to mitigate the impact of GATT on U.S. applicants' rights to a patent term,[4] Gilead Sciences was required to file this provisional in a separate family of applications. Subsequently, on December 27, 1996, Gilead Sciences filed U.S. non-provisional application no. 08/774,345 ("the '345 application"), which claimed priority to the '306 provisional and included the first specific claims to oseltamivir. (A30; A511; A530.) During prosecution of the '345 application, Gilead Sciences disclosed all of its prior-filed applications related to its neuraminidase inhibitor research, specifically the '245, '946 and '567 applications, the latter of which was filed on the same day as, and had substantially similar disclosure to, the '306 provisional. (A30; A512-13; A530.)

On June 9, 1998, the PTO awarded Gilead Sciences with its first patent based on its neuraminidase inhibitor research—the '483 patent—which issued from the '345 application. (A30; A510; A531.) Because the '345 application was filed several months ***after*** the June 8, 1995 effective date of the patent term

[4] Concurrent with the changes to the patent term made that year to implement GATT (discussed *infra*), 35 U.S.C. § 111 was amended to provide the option for filing of a provisional application. The purpose of this legislative change was to put U.S. applicants on parity with foreign applicants, who could claim a 12-month foreign filing benefit under the Paris Convention for the Protection of Industrial Property. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994).

amendments resulting from GATT,[5] the ’483 patent was granted a term that will expire twenty years after the December 27, 1996 filing date of the ’345 application, *i.e.*, on December 27, 2016. (A30, 508, 510.)

Meanwhile, on September 14, 1999—fifteen months after the issuance of the ’483 patent and after Gilead Sciences had filed a terminal disclaimer with respect to that first-issued patent—the PTO issued Gilead Sciences a second patent based on its neuraminidase inhibitor research—the ’375 patent, which issued from the ’624 application. (A151; A507.)[6] Although the earliest-filed application in the ’375 patent family—the ’245 application—had been filed several months ***before*** June 8, 1995 and therefore would have been subject to the pre-GATT patent term of seventeen years from issuance, the ’624 application from which the ’375 patent issued was filed several months ***after*** June 8, 1995 and is therefore subject to a post-GATT patent term expiring twenty years from the effective filing date, *i.e.*, the filing date of the ultimate parent ’245 application. (A508-10.) Thus, the ’375 patent is scheduled to expire on February 27, 2015, approximately 16 months

---

[5] The General Agreement on Tariffs and Trade (“GATT”), implemented by the Uruguay Round Agreements Act, changed the statutory patent term from 17 years from issuance, to 20 years from the effective filing date, for all patents filed after June 8, 1995. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994).

[6] The PTO also issued a patent on the ’946 application—U.S. Patent No. 5,866,601 (“the ’601 patent”). (A309.) The ’245 and ’567 applications were abandoned. (A367; A509.)

earlier than it would have expired absent the change in the patent term law brought about by GATT.[7] (A508.)

III. The District Court Granted Summary Judgment on Natco's Sole Invalidity Defense—Obviousness-Type Double Patenting Over the '375 Patent—and Awarded Final Judgment to Gilead.

After Natco provided notice that it had submitted an ANDA seeking FDA approval to market generic copies of certain TAMIFLU® dosage forms before the expiration of the '483 patent, together with a "Paragraph IV" certification with respect to that patent, Gilead commenced suit against Natco in the New Jersey district court. (A504-05.)[8] In the district court, Natco asserted only a single invalidity defense—obviousness-type double patenting over the '375 patent. (A506.) After the parties cross-moved for summary judgment on that defense, the district court granted Gilead's motion and denied Natco's cross-motion. (A1-9.) Noting that "the narrow issue before this Court is whether the '375 patent can be used as a reference patent for purposes of determining if the '483 patent is an

---

[7] Under pre-GATT law, the '375 patent would have been entitled to a seventeen-year term from its September 14, 1999 issue date, *i.e.*, until September 14, 2016.

[8] Although the '375 and '601 patents are also listed in the Orange Book with respect to Hoffmann-La Roche's NDA No. 21-087, Natco's ANDA does not seek approval to market its generic TAMIFLU® copies before the expiration of those patents, and Natco did not submit "Paragraph IV" certifications with respect to them. Accordingly, the '375 and '601 patents were not asserted by Gilead in this action.

unlawful extension of the ’375 patent,” the district court held that it could not. (A5-8.)

In reaching its conclusion, the district court considered two recent decisions of the Delaware district court, *Brigham & Women’s Hosp. Inc. v. Teva Pharms. USA, Inc.*, 761 F. Supp. 2d 210 (D. Del. 2011) and *Abbott Labs. v. Lupin Ltd.*, Civ. A. No. 09-152, 2011 WL 1897322 (D. Del. May 19, 2011), in which that court “had to address whether a later-issued but earlier-expiring patent can serve as a double-patenting reference against an earlier-issued but later expiring patent,” *i.e.*, the same issue presented here. (A6-7.) As the district court in this case noted:

> Both times, the Delaware district court held that a later-issued but earlier-expiring patent cannot be used as an invalidating reference against an earlier-issued but later-expiring patent ***because logically a later-issued patent cannot be extended by a patent that was already in existence***. *See Abbott Labs.*, 2011 WL 1897322 at *8; *Brigham & Women’s Hosp. Inc.*, 761 F. Supp. 2d at 226. ***Similarly here, the ’375 patent cannot serve as a reference patent as it issued after and terminates before the ’483 patent. Therefore, the ’483 patent does not unlawfully extend Gilead’s right to exclusivity.***

(A7.)[9]

The district court also considered Natco’s argument that the ’483 patent should somehow be declared invalid because it was obtained through Gilead Sciences’ “gamesmanship,” in particular its alleged non-disclosure of the application for the ’375 patent during prosecution of the ’483 patent. (A7-8

[9] All emphasis is added, unless otherwise indicated.

("Natco contends that had the PTO known about the '375 patent application, the patent examiner 'would have conditioned the allowance of the '483 patent on Gilead terminally disclaiming any term of the '483 patent that extended beyond twenty years after the filing date of the '375 patent'").) Although not critical to its summary judgment decision, the district court nevertheless summarily rejected Natco's argument, branding it "ineffective":

> Gilead notified the PTO of the '375 patent family of applications, including the '567 application, which contained a similar disclosure to the '306 provisional application. . . . Therefore, the nondisclosure of the '624 application, though it also contained a similar disclosure to the '306 provisional application, is not detrimental to Gilead's case because of Gilead's disclosure of the '567 application. Similar to *Abbott Labs.* and *Brigham*, the lifespan of Gilead's patents seem to be a result of changes in patent law, and not any gamesmanship from Gilead. ***Since the issuance of the '483 patent is not the result of any strategic abuse of the patent system by Gilead, the '375 patent cannot serve as a reference patent to invalidate the '483 patent because of obviousness-type double patenting.***

(A8.)

Because Natco had conceded infringement of claims 2 and 3 of the '483 patent, and had no other invalidity defense with respect to those claims, the parties agreed in the interest of efficiency to the entry of final judgment with respect to those claims, and the stay of Gilead's remaining infringement allegations. (A10-12.) On May 9, 2013, the district court entered final judgment that Natco infringed claims 2 and 3 of the '483 patent, and that claims 1-7 of the '483 patent are valid. (*Id.*) Natco filed its notice of appeal on May 20, 2013.

SUMMARY OF THE ARGUMENT

This appeal presents a narrow legal issue—whether a ***later-issued, earlier-expiring*** patent can be used as a reference patent for purposes of determining whether an ***earlier-issued, later-expiring*** patent is invalid under the doctrine of obviousness-type double patenting. According to almost 150 years of precedent, the answer is ***no***, as the district court correctly ruled.

Indeed, this Court has repeatedly confirmed that the purpose of the rule against double patenting is to prevent an inventor from effectively extending its term of exclusivity by the "***subsequent patenting***" of variations that are not patentably distinct from the "***first-patented invention***." In other words, the doctrine prohibits the issuance of claims in a "***second patent***" that are not patentably distinct from claims in a "***first patent***." As the U.S. Supreme Court stated almost 150 years ago, if double-patenting is established, the ***later-issued patent*** is invalid, ***not the first***. Where the validity of the ***first-issued patent*** is being challenged, the double patenting doctrine does not apply.

That is precisely the case here. The '483 patent-in-suit is the first patent issued to Gilead Sciences based on its neuraminidase inhibitor research. The '375 patent issued over a year later. The '483 patent is the ***first-issued patent*** that claims the ***first-patented invention***, and it cannot be invalid for obviousness-type double patenting over the later-issued '375 patent.

This result is entirely consistent with the policy underlying the double patenting doctrine, *i.e.*, avoiding unjustified, timewise extension of the term of exclusivity granted to the first-patented invention. Here, the PTO first granted a term of exclusivity to the invention claimed in the '483 patent, beginning with the patent's issuance on June 9, 1998, and ending with the patent's expiration on December 27, 2016, twenty years after the filing date of the application from which the '483 patent issued. That eighteen-and-a-half year term is well within the twenty-year maximum patent term provided under the post-GATT patent laws. And, because the term of the '375 patent—which issued after the '483 patent and is set to expire before the '483 patent—is entirely subsumed within the '483 patent term, the issuance of the '375 patent in no way extends the term of exclusivity for the '483 patent invention.

Natco now asks this Court to turn a century-and-a-half of precedent on its head, arguing that an accused infringer should be permitted to rely on a later-issued patent to truncate the term of an earlier-issued patent under post-GATT law. But, Natco concedes that its novel "reverse double patenting" theory is unsupported by ***any*** binding precedent. Nor are Natco's litigation-inspired policy arguments persuasive.

First, the conclusion correctly reached by the district court would in no way "permit extensions of patent terms beyond the statutory 20 years." On the

contrary, under post-GATT law, absent applicability of patent term extension provisions not at issue in this case, the term of protection provided by a patentee's first-issued patent will never expire more than twenty years after the effective filing date of the application from which it issued. That is the case here, where the first-issued '483 patent, subject to post-GATT law, is set to expire twenty years after the filing date of the '345 application from which it issued. If a patentee attempts to unjustifiably extend the term of its first-issued patent by way of a ***second patent*** on the same invention or an obvious variant, the correctly-applied double patenting doctrine will prevent issuance of, or invalidate, that ***second patent***. On the other hand, where (as here) the patentee's second patent expires ***before*** the first-issued patent, there is no timewise extension of the term of protection granted to the first-patented invention, and the double patenting doctrine is inapplicable. In either case, the obviousness-type double patenting doctrine cannot be relied upon to invalidate the ***first-issued patent*** (in this case, the '483 patent-in-suit) as a matter of law.

Second, Natco's assertion that the district court's conclusion "would have the unfortunate consequence of encouraging gamesmanship during the application process" is without basis. Indeed, conclusory attorney argument aside, Natco does not explain how or why the district court's conclusion would allow applicants to "manipulate priority, issuance and expiration dates." It is well-settled that an

inventor may file a new patent application on an improvement of an earlier invention. And, there is no rule requiring the improvement to be claimed in the same family as the earlier application; the applicant has a choice to claim the improvement in an unrelated application but must face the resulting consequences—loss of the right to claim priority to the earlier application and exposure to additional prior art. Indeed, to take advantage of the post-GATT provisional procedure, as Gilead Sciences did here, an applicant ***must*** file the improvement application in a separate family. That procedure was implemented by Congress to harmonize patent laws globally and to ensure that U.S. applicants are not disadvantaged compared to foreign applicants who may claim an earlier priority date based on a foreign-filed application. Gilead Sciences, thus, was simply taking advantage of the new procedure just as Congress intended U.S. patent applicants to do.

Furthermore, once the applicant has made its choice, it is the ***PTO*** that ultimately decides if and when a patent application will issue; the applicant cannot know when the PTO might grant each of its copending applications. And, even if the applicant could somehow control which patent application issued first, where (as here) the patentee is granted no more than the statutory twenty-year term of exclusivity for the first-patented invention to which it is entitled under the law, the policy behind the obviousness-type double patenting doctrine is fulfilled.

Third, the district court's conclusion would not "allow multiple suits by different assignees asserting essentially the same invention." On the contrary, consistent with the well-established principles underlying the obviousness-type double-patenting doctrine, after a ***first*** patent issues claiming the patentee's invention, the patentee may be required to file a terminal disclaimer before issuance of a ***second*** patent. Indeed, that is precisely what occurred in this case—after the '483 patent issued, Gilead Sciences was required to submit a terminal disclaimer to secure subsequent issuance of the '375 patent. By filing the terminal disclaimer to secure issuance of the ***second patent*** (in this case, the '375 patent), the patentee not only disclaims any portion of the term of the second patent beyond the expiry of the first-issued patent (in this case, the '483 patent)—thereby ensuring that the term of that first-issued patent is not unjustifiably extended by issuance of the second patent—but also agrees that the second patent is enforceable only when commonly owned with the first-issued patent. This appropriately precludes any possibility of "multiple suits by different assignees asserting essentially the same invention."

Finally, the fact that post-GATT changes to the patent law have provided patentees with certain pre-issuance rights does not justify the fundamental re-writing of obviousness-type double patenting jurisprudence requested by Natco. As an initial matter, even pre-GATT, a patent's filing date provided the patentee

with important pre-issuance rights vis-à-vis priority of invention and novelty. Thus, the amendments to the provisions governing priority and novelty brought in by the Leahy-Smith America Invents Act ("AIA") earlier this year do not justify Natco's requested change to the basis for obviousness-type double patenting under post-GATT law. Furthermore, when making each of the changes to the patent law relied upon by Natco, Congress was well-aware of the obviousness-type double patenting doctrine and its long-settled reliance on issue dates rather than filing dates for determining priority of commonly-owned patents. Yet Congress did not amend the doctrine to permit the novel invalidity defense Natco seeks here.

In this case, on issuance of the '483 patent, the public was given full and fair notice of the term of exclusivity granted to the first-patented invention claimed in that patent, which expires twenty years from the effective filing date of that patent in complete accordance with post-GATT patent term law. And, because the later-issued '375 patent expires ***before*** the first-issued '483 patent, the '375 patent does not provide ***any*** timewise extension of protection for the first-patented invention—the term of exclusivity for that invention is the same as it would have been had the '375 patent never issued.

In sum, because the district court correctly ruled, consistent with long-standing precedent, that the later-issued, earlier-expiring '375 patent may not be used as a reference patent for purposes of determining whether the earlier-issued,

later-expiring ’483 patent-in-suit is invalid for obviousness-type double patenting—the only invalidity argument raised by Natco below—the district court’s final judgment should be affirmed.

STANDARD OF REVIEW

This Court reviews a grant of summary judgment *de novo*. *See ICU Med., Inc. v. Alaris Med. Sys. Inc.*, 558 F.3d 1368, 1374 (Fed. Cir. 2009). Summary judgment is appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

Obviousness-type double patenting is an issue of law that is generally premised on underlying factual inquiries. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012) (citation omitted). This court considers the district court's ultimate conclusion on obviousness-type double patenting without deference, but reviews any predicate findings of fact for clear error. *Id.*

ARGUMENT

I. According to 150 Years of Precedent, the Later-Issued, Earlier-Expiring '375 Patent Cannot Be Used as a Double Patenting Reference Against the Earlier-Issued, Later-Expiring '483 Patent-In-Suit.

"The purpose of the rule against double patenting is to prevent an inventor from effectively extending the terms of exclusivity by the ***subsequent patenting*** of variations that are not patentably distinct from the ***first-patented invention***." *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996). In other words, "[t]he doctrine of obviousness-type double patenting is intended to 'prevent the extension of the term of a patent . . . by prohibiting the ***issuance*** of the claims in a ***second patent*** not patentably distinct from the claims of a ***first patent***." *Teva Parenteral Meds.*, 689 F.3d at 1376 (quoting *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985)). It follows that where a patent being challenged is the "***first patent***" claiming the "***first-patented invention***," the doctrine does not apply.

This principle has been well-settled for almost a century-and-a-half, since the U.S. Supreme Court's decision in *Suffolk Co. v. Hayden*, 70 U.S. 315 (1865). In that case, the patentee, Hayden, had filed an application for a patent on improvements in cotton cleaners in December 1854. *Id.* at 315. When the Patent Office did not act on this first application for several years, Hayden filed a second application in June 1857 on what the trial judge ruled to be the same invention as

claimed in the first application. *Id.* at 316. The Patent Office granted Hayden his first patent on this second application in December 1857. *Id.* Almost three years later, the Patent Office finally granted Hayden his second patent on his first application in September 1860. *Id.* After Hayden brought suit on the ***later filed, but earlier-issued*** patent, the defendant argued that the asserted patent was invalid for double-patenting over the ***earlier-filed, but later-issued*** patent allegedly claiming the same invention. *Id.* at 319. The Supreme Court rejected this argument as a matter of law:

> This original application before the commissioner for a patent, among other things, for an improvement in the screen of the long trunk, not having been acted upon by that officer, a new application was made by Hayden, separately, for this improvement, and which resulted in the patent of 1st December, 1857, on which the present suit is brought.
>
> We do not perceive any objection to this proceeding. It simplified the application, and disembarrassed it from its connection with other improvements claimed; and, doubtless, hastened the granting of the patent. The office, however, subsequently acted upon this original application, and, on the 11th September, 1860, granted a patent to the plaintiff, and, as is alleged, for the same improvement embraced in the patent of the 1st December, 1857, the one in question. ***And it is insisted that, for this reason, this prior patent for the same improvement is void. This is, obviously, a misapprehension. The last, not the first, is void.***

Id.

The *Suffolk* Court's holding was succinctly summed up in the subsequent U.S. Supreme Court decision in *Miller v. Eagle Mfg. Co.*:

> Thus, in Manufacturing Co. [*sic*] v. Hayden, 3 Wall 315, it was held that where two patents, showing the same invention or device, were issued to the same party, ***the later one was void, although the application for it was first filed***; thereby deciding that ***it is the issue date, and not the filing date***, which determines priority to patents issued to the same inventor on the same machine.

151 U.S. 186, 197 (1894). The Supreme Court explained that the reason for the rule was that "the power to create a monopoly is exhausted by the ***first patent***, and for the further reason that a ***new and later patent*** for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." *Id* at 198. Thus, the U.S. Supreme Court rejected the very theory that Natco raises here—that the filing date determines priority of patents issued to the same inventor on the same invention, and a first-issued patent may be invalidated for double patenting over a later-issued patent.

Since *Suffolk* and *Miller*, courts, including this Court, have consistently framed the issue as whether the ***later-issued*** patent is invalid for double patenting. For example, in *Symbol Techs., Inc. v. Opticon, Inc.*, this Court explained that the "judicially created doctrine of obviousness-type double patenting applies when two applications or patents, not drawn to precisely the same invention, are 'drawn to inventions so very much alike as to render one obvious in view of the other and ***to effectively extend the life of the patent that would have the earlier of the two issue dates***.'" 935 F.2d 1569, 1580 (Fed. Cir. 1991) (quoting *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 686 (Fed. Cir. 1990)). More recently,

this Court stated in *Eli Lilly & Co. v. Barr Labs., Inc.* that "[a] ***later claim*** that is not patentably distinct from an ***earlier claim*** in a commonly owned patent is invalid for obviousness-type double patenting." 251 F.3d 955, 968 (Fed. Cir. 2001); *see also Georgia-Pac. Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999) ("Under obviousness-type double patenting, a patent is invalid when it is merely an obvious variation of an invention disclosed and claimed in an ***earlier patent*** by the same inventor"). And, in the recent case of *Sun Pharm. Indus. Ltd. v. Eli Lilly & Co.*, this Court stated that:

> ***"[A]ll proper double patenting rejections***, of either type, rest on the fact that ***a patent has been issued*** and ***later issuance*** of a ***second patent*** will continue protection, beyond the date of expiration of the ***first patent"*** of the same invention or an obvious variation thereof.

611 F.3d 1381, 1389 (Fed. Cir. 2010) (quoting *In re Kaplan*, 789 F.2d 1574, 1579-80 (Fed. Cir. 1986)). Notably, this Court has commented that a later-issued but earlier-expiring patent presumably cannot be used as an obviousness-type double patenting reference against an earlier-issued but later-expiring patent:

> We note that, because the '933 patent issued on August 20, 1996, which was before the issuance of the '698 patent on April 8, 1997, the '698 patent presumably ***cannot be used as an obviousness-type double patenting reference against the '933 patent on remand.***

Amgen Inc. v. F. Hoffmann-La Roche Ltd., 580 F.3d 1340, 1354 n.5 (Fed. Cir. 2010) (citing *Georgia-Pac.*, 195 F.3d at 1326).[10]

According to these well-settled principles, then, it is the ***issuance*** of the first patent that signals the beginning of term of protection for the patentee's invention. *See Miller*, 151 U.S. at 197; *see also, e.g., General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1282 (Fed. Cir. 1992) (noting that the obviousness-type double-patenting doctrine is "intended to prevent unjustified *extension* of ***protection***," which begins on the first patent's issuance). If a second patent subsequently issues to the same inventors, the question for obviousness-type double patenting purposes is whether the ***second patent*** provides an "'unjustified timewise extension of the right to exclude'" granted by the ***first patent***. *See, e.g., In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (quoting *In re Van Ornum*, 686

[10] Natco's reliance on *Takeda Pharm. Co., Ltd. v. Doll*, 561 F.3d 1372 (Fed. Cir. 2009) is misplaced. (*See* Blue Br. at 11.) In *Takeda*, this Court was considering "the relevant time frame for determining whether a product and process are 'patentably distinct,'" not whether an earlier-filed, but later-issued patent can be relied upon as a double patenting reference. *See Takeda*, 561 F.3d at 1377. Moreover, the *Takeda* court's comment that the filing of the second application "actually ***triggers*** the potential" of a double patenting issue is uncontroversial and entirely consistent with the district court's conclusion in this case. *Id.* (emphasis in original). Indeed, before a second patent application is filed by the patentee, there is only a single application claiming the patentee's invention, and by definition there cannot be even the potential for a double-patenting issue.

F.2d 937, 943-44 (C.C.P.A. 1982)).[11] Even assuming the claims of the two patents are not patentably distinct, if the second-issued patent expires ***before*** the first-issued patent, there is no timewise extension of the right to exclude granted by the first patent and the obviousness-type double patenting doctrine is inapplicable. *Id.* On the other hand, if the second-issued patent expires ***after*** the first-issued patent, the obviousness-type double patenting doctrine could apply to invalidate the ***second-issued patent***. *Id.* In either case, the ***first-issued patent*** remains valid. *See Suffolk*, 70 U.S. at 319.[12]

---

[11] Notably, as Natco concedes, *In re Hubbell* addressed a situation where the patent and application at issue were both filed under the post-GATT regime. (*See* Blue Br. at 23 n.10.) Yet, this Court still noted that the obviousness-type double patenting doctrine "prohibits the issuance of claims in a ***second patent*** that are 'not patentably distinct from the claims of the ***first patent***.'" *In re Hubbell*, 709 F.3d at 1145 (quoting *In re Longi*, 759 F.2d at 892).

[12] The additional cases relied upon by Natco describe the principles underlying the doctrine similarly. *See, e.g.*, *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012) ("Nonstatutory double patenting is a judicially created doctrine grounded in public policy that 'prevent[s] the extension of the term of a patent, even where an express statutory basis for the rejection is missing, by prohibiting the issuance of the claims in a ***second patent*** not patentably distinct from the claims of the ***first patent***.") (quoting *In re Longi*, 759 F.2d at 892); *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010) ("'The judicially-created doctrine of obviousness-type double patenting cements [the] legislative limitation [of § 101] by prohibiting a party from obtaining an extension of the right to exclude through claims in a ***later patent*** that are not patentably distinct from claims in a commonly owned ***earlier patent***'") (quoting *Eli Lilly v. Barr*, 251 F.3d at 967); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008) (similar); *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003) (obviousness-type double patenting is intended "to ***prevent***

Applying these well-settled principles in this case confirms the correctness of the district court's conclusion. It is undisputed that the '483 patent was the first patent to issue claiming oseltamivir—indeed, it was the first patent to issue with respect to ***any*** of Gilead Sciences' neuraminidase inhibitor research. (A30; A510; A531.) The '375 patent issued over a year later. (A151; A507.) Thus, the '483 patent is the "***first patent***," claiming the "***first-patented invention***," with "***the earlier of the two issue dates***," and it cannot be invalid for obviousness-type double patenting in light of the later-issued '375 patent as a matter of law.[13]

II. Natco's "Reverse Double Patenting" Defense is Unsupported by *Any* Binding Precedent.

Notwithstanding this long-standing precedent, Natco now argues that it should nevertheless be permitted to rely on the later-issued '375 patent as a double patenting reference against the first-issued '483 patent under the circumstances of

---

issuance of a patent on claims that are nearly identical to claims in an ***earlier patent***."); *In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998) (obviousness-type double patenting is intended "to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a ***second patent*** claiming an obvious variant of the same invention ***to issue to the same owner later***"); *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997) ("An obviousness-type double patenting rejection prevents applicants from extending their patent term beyond statutory limits where ***an application*** claims merely an obvious variant of the claims in a ***prior patent***.").

[13] Nor is the later-issued '375 patent invalid for obviousness-type double patenting over the earlier-issued '483 patent. The '375 patent expires ***before*** the '483 patent, and therefore does not provide a timewise extension of the right to exclude granted by the '483 patent. *See In re Hubbell*, 709 F.3d at 1145.

this case. But Natco concedes that this type of "reverse double patenting" argument has never been endorsed by this Court. (Blue Br. at 22-23.) It also has been expressly rejected by the only court to explicitly consider the issue, in two cases remarkably similar to the case at hand. *See Brigham*, 761 F. Supp. 2d at 225; *Abbott Labs.*, 2011 WL 1897322, at *10.

Like Natco in this case, the defendant in *Brigham* argued that two earlier-issued patents-in-suit were invalid for obviousness-type double patenting over a third, later-issued patent, on the ground that the first two patents, due to their later expiration, "impermissibly extend patent protection . . . beyond the term granted by the [later-issued] patent." *Brigham*, 761 F. Supp. 2d at 224. In rejecting the defendant's arguments, the Delaware court noted that "[a]lthough plaintiffs could not know when or if the PTO might grant each of the three patents, the possibility always existed that the [earlier-issued] patents would have longer terms than the [later-issued] patent." *Id.* at 225. And, as the court went on to note, the disparity in issuance and expiration dates was due solely to "legal changes to the patent terms, the timing of the applications, and the length of prosecution." *Id.* In such circumstances, the later-issued patent "could not and did not create an 'unjustified timewise extension'" of the earlier-issued patent. *Id.*

In reaching this conclusion, the *Brigham* court rejected the reasoning in a prior decision of the Board of Patent Appeals and Interferences ("BPAI")—*Ex*

Parte Pfizer, No. 2009-4106, 2010 WL 532133 (B.P.A.I. Feb. 12, 2010)—in which the BPAI had found that two later-issued, earlier-expiring patents could serve as double patenting references against an earlier-issued, later-expiring patent:

> The court is not persuaded by the Board's reasoning [in *Pfizer*]. The Board argues that the double-patenting doctrine is designed to prevent unjust extension of a patent term, but its opinion makes no effort to explain why the shorter period must prevail. The opinion does not explain why a later-issued patent with a shorter term should be used to abridge the term of a valid, earlier-granted patent with a longer term.

Brigham, 761 F. Supp. 2d at 225.

The Delaware district court reached a similar conclusion in its subsequent decision in *Abbott Labs*. In that case, the defendant asserted a later-issued, earlier-expiring patent as a double patenting reference against the earlier-issued, later-expiring patent-in-suit. *Abbott Labs.*, 2011 WL 1897322, at *8. Agreeing with *Brigham*, the court rejected this defense as a matter of law:

> Abbott has obtained no timewise extension of the earlier-issued but later-expiring [patent] through the [later-issued, earlier-expiring patent]; ***the term of the [earlier-issued, later-expiring] patent is the same as it would have been had the [later-issued, earlier-expiring] patent never issued.***

Id. at *10.

Natco asks this Court to ignore the Delaware court's reasoning on the ground that *Brigham* and *Abbott Labs.* involved "the peculiar mixture of commonly owned pre-GATT and post-GATT patents." (*See* Blue Br. at 23; *see also id.* at 26-27 ("*Brigham* and *Abbott* in particular were decided explicitly on the

grounds that the double patenting issue had been created by the change in the patent laws.").) But, to the extent that the Delaware court's reasoning in *Brigham* and *Abbott Labs.* is so limited, it is still equally applicable here. In this case, the ultimate parent application from which the '375 patent claims priority—the '245 application—was filed ***before*** the amendments to the patent term brought about by GATT were in force. (A358-65; A508; A529.) While Gilead Sciences was working on the improvements that were ultimately claimed in the '375 and '483 patents, the law changed such that those patents are subject to the post-GATT patent term of twenty years from the effective filing date. (A508-09.) Absent that change in the law, both patents would have been entitled to terms of seventeen years from issuance, and the later-issued '375 patent would have expired ***after*** the earlier-issued '483 patent, indisputably disqualifying it as a double patenting reference. Thus, as in *Brigham* and *Abbott Labs.*, the disparity in the issuance and expiration dates of the '375 and '483 patents is also due to "legal changes to the patent terms, the timing of the applications, and the length of prosecution." *See Brigham*, 761 F. Supp. 2d at 225.

In any event, the Delaware court's reasoning in *Brigham* and *Abbott Labs.* is equally applicable to cases where both patents at issue, and the applications from which they claim priority, are subject to post-GATT patent terms. Indeed, the *Brigham* court found it particularly significant that "even if the claims in the [later-

issued, earlier-expiring] patent were identical to those in the [earlier-issued, later-expiring] patents, the [later-issued, earlier-expiring] patent's term could not extend the patent protection to which plaintiffs were already entitled on the [earlier-issued, later-expiring] patents." *Brigham*, 761 F. Supp. 2d at 225. This is equally true where the patents at issue are both subject to the post-GATT term of twenty years from the effective filing date—a later-issued, earlier-expiring patent cannot extend the term of protection afforded by an earlier-issued, later-expiring patent. Also equally true in a case involving only post-GATT patents and applications is the *Abbott Labs.* court's observation that "[the patentee] has obtained no timewise extension of the earlier-issued but later expiring [] patent through the [later-issued, earlier-expiring] patent; the term of the [earlier-issued, later expiring] patent is the same as it would have been had the [later-issued, earlier-expiring] patent never issued." *Abbott Labs.*, 2011 WL 1897322, at *10. In sum, as the Delaware district court held, so long as the patentee is not granted more than a twenty year term for its first-patented invention, there is no reason that a later-issued patent with a shorter term should be used to abridge the term of the otherwise valid, earlier-granted patent with a longer term. *Brigham*, 761 F. Supp. 2d at 225; *Abbott Labs.*, 2011 WL 1897322, at *10.

Natco concedes that "[t]he GATT amendments did not alter the basis for the obviousness-type double-patenting doctrine." (Blue Br. at 23 n. 11.) And Natco

also concedes that "the legislative history leading up to the GATT amendments reflects that Congress understood and intended for the doctrine to continue, consistent with the Act's statutory text." (*Id.* (citing S. Rep. No. 103-412, pt. IV at 228-29 (1994)).) Yet, despite admitting that Congress was aware of the issue, Natco points to no evidence, in the legislative history leading to the GATT amendments or otherwise, that Congress intended to fundamentally change over a century of obviousness-type double-patenting jurisprudence to permit reliance on a later-issued patent to invalidate an earlier-issued patent. On the contrary, as this Court has commented, after the change in patent term from seventeen years from issuance to twenty years from filing, the obviousness-type double patenting doctrine has "limited force," and generally applies only in limited circumstances after GATT (patent term adjustment under 35 U.S.C. § 154 or patent term extension under 35 U.S.C. § 156)—circumstances not present in this case. *See In re Fallaux*, 564 F.3d 1313, 1318-19 (Fed. Cir. 2009). At base, in the absence of any such clear statement of legislative intent, Natco's contention that the GATT amendments to the patent term also, ***by implication***, fundamentally changed the basis for the obviousness-type double patenting doctrine, falls flat. *Cf. Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188, 2198-99 (2011) ("We are confident that if Congress had intended such a sea change in intellectual property rights it would have said so clearly . . . .") (citing

Whitman v. Am. Trucking Assns., Inc., 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.")).

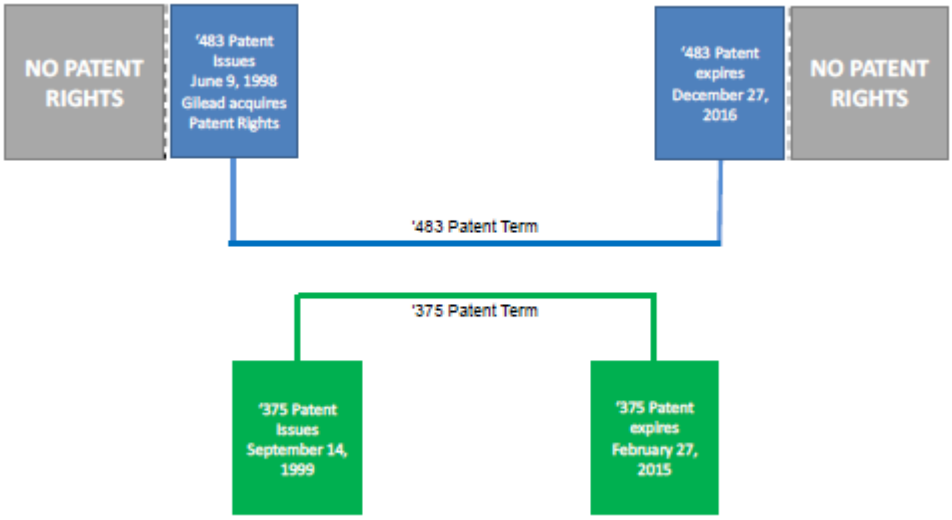
III. Natco's Policy Arguments are Unpersuasive and Cannot Justify its Requested "Sea Change" in Obviousness-Type Double Patenting Jurisprudence.

Lacking ***any*** legislative or precedential support for its novel "reverse double patenting" theory, Natco propounds a series of policy arguments as to why this Court should now take it upon itself to overturn 150 years of precedent and create an entirely new ground of patent invalidity. None is persuasive.

First, Natco argues that the district court's conclusion would extend the term of the '375 patent beyond twenty years from its effective filing date, and therefore "present[] a definitive example of an unjustified time-wise extension of a patent term." (Blue Br. at 13-15; *see also id.* at 18-19 ("Gilead's theory would undeniably permit the 20 year patent term for the invention claimed by the '375 patent to be extended by 22 months.").) Natco's argument is premised on the notion that the term of protection that the obviousness-type double patenting doctrine is intended to limit stretches from the filing date of the first-filed application to the expiration date of the last-expiring patent. Natco's position is at odds both with the Patent Act and with longstanding double patenting precedent.

Patents confer on the patentee the right to exclude others from practicing their claimed invention from issuance of the patent until its expiry. 35 U.S.C. 154(b). Patent applications confer no such rights; thus the right to exclude does not begin unless, and until, a patent issues. *See, e.g.*, *Marsh v. Nichols, Shepherd & Co.*, 128 U.S. 605, 612 (1888) ("Until the patent is issued there is no property right in it; that is, no such right as the inventor can enforce."); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1581 (Fed. Cir. 1997) ("[T]he right to exclude does not inure until the patent issues."); *GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996). Because the obviousness-type double-patenting doctrine is "intended to prevent unjustified *extension* of ***protection***" of an invention, which does not begin until a patent issues, the doctrine rightly focuses on the term of protection from ***issuance***, not from ***filing***. *See General Foods*, 972 F.2d at 1282; *see also Miller*, 151 U.S. at 197.

Here, the '483 patent was the first patent awarded to Gilead Sciences in connection with its neuraminidase inhibitor research. The term of protection for Gilead Sciences' inventions began the day the '483 patent issued. At that time, there was no '375 patent. Since no '375 patent existed when the '483 patent issued, there was no '375 patent term for the '483 patent to extend. It was not until September 14, 1999, more than ***15 months after*** the '483 patent term began, that the '375 patent issued:



As illustrated by the above graphic, the ’375 patent term is completely subsumed within the term of the ’483 patent. Thus, the full term of Gilead Sciences’ patent rights would have been the same, whether or not the ’375 patent ever issued.

Natco complains that “[t]he public should . . . be able to act on the assumption that upon the expiration of the [’375] patent it will be free to use not only the invention claimed in the patent but also [obvious] modifications or variants . . . .” (Blue Br. at 15 (paraphrasing *In re Longi*, 759 F.2d at 892-93).) But Natco does not explain why the public would rely on the expiration of the later-issued ’375 patent. When the ’483 patent issued—over a year prior to the ’375 patent—the public had full and fair notice that Gilead Sciences had been awarded rights to the claimed compounds for a statutory term under post-GATT law extending until twenty years from the filing date of that application, *i.e.*, through December 27, 2016. Thus, the public would properly understand that it would not

be free to use the compounds of the ’483 patent until after that date. When the ’375 patent issued over a year after the ’483 patent, it did nothing to alter that understanding. Notably, Natco’s selective paraphrasing from *In re Longi* conveniently ignores the Court’s statement, immediately prior, that the purpose of an obviousness-type double patenting rejection is to prohibit “the issuance of the claims in a ***second patent*** not patentably distinct from the claims of the ***first patent***.” *In re Longi*, 759 F.2d at 892 (citations omitted). Thus, assuming it is familiar with the obviousness-type double patenting doctrine, the public would not expect that it could be applied to invalidate a patentee’s first-issued patent.[14]

Natco’s assertion that Gilead gets both the earlier priority and the later expiration for its claimed invention is incorrect. (Blue Br. at 15, 21.) On the contrary, by choosing to file the application for the ’483 patent separate from the ’375 patent family, Gilead Sciences waived any entitlement to rely on the earlier priority date of the ’375 patent family. In that regard, *Abbott Labs. v. Novopharm*

---

[14] Although the public might have an interest in “the earlier expiration of patents whereby the inventions covered become freely available to the public” (*see* Blue Br. at 25 n.12 (quoting *In re Berg*, 140 F.3d at 1436)), that public interest does not trump the patentee’s legitimate expectation that, in return for disclosing a new, useful invention, it will receive the full benefit of the statutory term of exclusivity allowed under the patent laws, *i.e.*, until twenty years after the effective filing date of that patent under post-GATT law. *See, e.g.*, *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (“[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.”).

Ltd., 104 F.3d 1305 (Fed. Cir. 1997), supports ***Gilead's*** position, not Natco's. (*Contra* Blue Br. at 21.) In that case, the patentee argued that its twenty-year patent term for the patent-in-suit should not date back to the filing date of its parent application because it "received no benefit from the divisional application." *Id.* at 1308. This Court rejected that argument, noting that:

> The district court found that [the patentee] chose to designate its patent as divisional in order to receive the potential benefits associated with the earlier filing date. [The patentee's] choice to do so cannot be disregarded simply because it subsequently found that the later filing date would be more advantageous. [The patentee] must accept the consequences as well as the potential benefits of the divisional status of the [patent-in-suit].

Id. Here, in contrast, Gilead Sciences chose ***not*** to designate the application for the '483 patent as related to the applications in the '375 patent family, thereby waiving the potential benefits associated with the earlier effective filing date of those applications. (A30; A151; A529.) Indeed, Natco could have relied on prior art published ***after*** that effective filing date to try to invalidate the '483 patent. But Natco did not do so. In fact, Natco has not cited any prior art against the '483 patent. Given that the '483 patent received no benefit from the '375 patent family's earlier effective filing date there is no reason that the term of the '483 patent should be truncated based on the '375 patent family's earlier effective filing date.

Natco relies on § 804 I.B.1 of the Manual of Patent Examining Procedure (MPEP), by which, according to Natco, "patent examiners are instructed to allow the first-filed application to issue with the full 20 year patent term and restrict the second-filed application to a term that ends when the first-filed patent term ends." (Blue Br. at 16.) Indeed, according to that MPEP provision, an examiner faced with two pending, commonly-owned applications subject to "provisional" obviousness-type double patenting rejections is instructed to require a terminal disclaimer to be filed with respect to the later-***filed*** application, even if that application is otherwise in condition for allowance before the earlier-filed application. (Blue Br. at 16 (quoting MPEP § 804 I.B.1).)[15] As an initial matter, MPEP § 804 I.B.1 is inapplicable in this case, because the application for the '483 patent was never subject to an obviousness-type double patenting rejection.[16] In any event "[t]he MPEP sets forth PTO procedures; it is not a statement of law."

---

[15] "If a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, ***a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn***." MPEP § 804 I.B.1 (first paragraph).

[16] As noted *infra*, Natco's argument below that the only reason that the examiner did not issue an obviousness-type double patenting rejection is that he was not made aware of the co-pending application for the '375 patent is contrary to fact and law, and was correctly rejected by the district court. (*See* Section IV, *infra*.)

Regents of Univ. of N.M. v. Knight, 321 F.3d 1111, 1121 (Fed. Cir. 2003) (citation omitted). Thus, "the MPEP does not have the force of law, and is only entitled to judicial notice as the PTO's official interpretation of statutes and regulations with which it is not in conflict." *Belkin Int'l, Inc. v. Kappos*, 696 F.3d 1379, 1384 (Fed. Cir. 2012). Here, the provision relied upon by Natco is not interpreting any applicable statute or regulation. On the contrary, Natco concedes that its double patenting theory purportedly supported by the MPEP is otherwise unsupported by ***any*** binding precedent. (*See* Blue Br. at 22-23.)

Moreover, Natco's relied-upon MPEP provision is directly contrary to this Court's rulings. *See, e.g.*, *Sun Pharm.*, 611 F.3d at 1389 ("'***[A]ll proper double patenting rejections***, of either type, rest on the fact that a patent has been ***issued*** and ***later issuance*** of a ***second patent*** will continue protection, beyond the date of expiration of the ***first patent***' of the same invention or an obvious variation thereof."). It is also inconsistent with the policy underlying the obviousness-type double patenting doctrine. Indeed, as discussed above, the doctrine serves to prevent an "unjustified timewise extension of the right to exclude" granted to a patentee, which commences only on ***issuance*** of a patent. *See, e.g.*, *In re Hubbell*, 709 F.3d at 1145; *General Foods*, 972 F.2d at 1282. An application that has not yet issued, and which in fact may never issue, provides no right to exclude. *Marsh*,

128 U.S. at 612; *Gargoyles*, 113 F.3d at 1581; *GAF Bldg. Materials*, 90 F.3d at 483.

Furthermore, according to the obviousness-type double patenting doctrine, the ***claims*** of the reference patent are compared to the ***claims*** of the challenged patent; the similarity between the two patents' specifications is irrelevant. *See Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010) ("The primary inquiry in double patenting cases is therefore whether the ***claims*** in the latter patent are more than a 'slight variant' from the ***claims*** in the earlier patent") (citation omitted); *General Foods*, 972 F.2d at 1277 ("Double-patenting is altogether a matter of what is claimed."); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 943 (Fed. Cir. 1992) ("[I]t is the claims that are compared when assessing double patenting."). Before any patent is issued on an application, however, the application's claims are subject to change, and indeed may be rejected outright and never issue. *See, e.g.*, *GAF Bldg. Materials*, 90 F.3d at 483 ("[A] patent does not exist until it is granted . . . . Patent rights are created only upon the formal issuance of the patent; thus, disputes concerning patent validity and infringement are necessarily hypothetical before patent issuance."). If no second patent issues, there can be no suggestion that the first-issued patent improperly extends the scope of protection afforded by a claim that does not, and will not, exist (and therefore provides no protection whatsoever). Under these circumstances, there is no basis

to require a patentee to terminally disclaim the claims of its later-filed application based on purported obviousness over non-final claims pending in an earlier-filed application that may or may not issue and, even if eventually issued, may be in an entirely different form. And, thus, Natco cites no MPEP section that would require an examiner to issue a double patenting rejection in the circumstances of this case.

Under these circumstances, where an inapplicable MPEP provision is contrary to both policy and precedent, there is no basis for this Court to take judicial notice of it. *See, e.g., Racing Strollers, Inc. v. TRI Indus., Inc.*, 878 F.2d 1418, 1422 (Fed. Cir. 1989) (rejecting citation to MPEP provision that was contrary to law). The law requires a terminal disclaimer to be filed before granting to a patentee a ***second-issued patent*** with claims that are not patentably distinct from a ***first-issued*** patent. *See In re Hubbell*, 709 F.3d at 1145; *Teva Parenteral Meds.*, 689 F.3d at 1376.

Not only does this avoid any timewise extension of the term of protection granted to the first-patented invention by virtue of the second-issued patent, but it also addresses Natco's second policy concern—that the district court's conclusion could result in "multiple suits by different assignees asserting essentially the same invention." (Blue Br. at 9, 19-20 (citing *In re Hubbell*, 709 F.3d at 1145; *In re*

Fallaux, 564 F.3d at 1318-19).)[17] Indeed, as Natco notes, a terminal disclaimer filed with respect to any such subsequent patent would need to include a provision that the patent is enforceable only for and during the period that the subsequent patent is commonly owned with the first-issued patent. (Blue Br. at 19 (citations omitted).) That is precisely what occurred in this case—before issuance of the '375 patent, Gilead Sciences was required to file a terminal disclaimer which disclaimed any term of that patent extending beyond the expiration date of the '483 patent, and confirmed "that any patent granted on [the] '624 application ***will be enforceable only during the period that the legal title to the '483 patent . . . is the same as the legal title to any patent granted on [the] '624 [application]***." (A546-47.) Under these circumstances, Natco's claim that the district court's conclusion could result in "multiple suits by different assignees asserting essentially the same invention" is entirely illusory.[18]

---

[17] Even if Natco's argument regarding the potential for "multiple suits by different assignees asserting essentially the same invention" had merit—which it does not—it is waived because Natco did not raise it before the district court. *See, e.g.*, *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1359-60 (Fed. Cir. 2012) (argument not raised by defendant in opposing summary judgment is waived).

[18] Natco's assertion that "the public's reasonable expectation is that no ***later-filed*** patent could claim an obvious modification of an invention claimed in an ***earlier-filed*** patent without a terminal disclaimer" (Blue Br. at 15 n. 5) is self-serving and illogical. To the extent that the public is familiar with the obviousness-type double patenting doctrine, the public would be aware of the long-standing principle that the doctrine in fact prohibits a ***later-issued*** patent

Natco next argues that "there are very significant patent rights prior to the issuance of a patent," pointing in particular to the new priority and novelty provisions under the AIA, and the provisional rights provisions under 35 U.S.C. § 154(d). (Blue Br. at 20.) As an initial matter, this argument too was not raised before the district court, and is therefore waived. *See, e.g.*, *Marine Polymer Techs.*, 672 F.3d at 1359-60. And, it is unavailing in any event. Indeed, the importance of a patent's effective filing date for priority and novelty purposes not only pre-dated the enactment of the AIA, but it also pre-dated the implementation of GATT. *See, e.g.*, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) ("[A]s has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed."). Thus, a patent's effective filing date cannot justify a fundamental, post-GATT shift in the basis for obviousness-type double patenting.

Furthermore, as with the implementation of GATT, although Natco concedes that Congress was aware of the obviousness-type double patenting doctrine when enacting the AIA (*see, e.g.*, Blue Br. at 20 n. 8), and was presumably also aware of the doctrine when the "provisional rights" provisions of

---

with claims that are not patentably distinct from those of an ***earlier-issued*** patent without a terminal disclaimer of any term beyond the expiration of the ***earlier-issued*** patent. *See, e.g.*, *Miller*, 151 U.S. at 197; *Sun Pharm.*, 611 F.3d at 1389.

35 U.S.C. § 154(d) were added to the Patent Act in 1999, Natco again points to no evidence that Congress intended those patent law amendments to effect drastic change to the obviousness-type double patenting doctrine in the manner asserted by Natco. Indeed, despite enacting a sweeping, fundamental change in the bases for asserting invalidity over the prior art in the AIA, Congress left the obviousness-type double patenting doctrine alone. Thus, as with the implementation of GATT discussed above, the changes to the patent laws implemented by the AIA and the enactment of 35 U.S.C. § 154(d) provide no basis for Natco's requested "sea change" in obviousness-type double patenting jurisprudence. *Cf. Bd. of Trustees of Leland Stanford Junior Univ.*, 131 S. Ct. at 2198-99.

Finally, Natco baldly asserts that the district court's conclusion "would invite applicants to engage in gamesmanship during the application process." (Blue Br. at 21-22.) But, it is well-settled that a patentee may file a later patent application claiming improvements of an invention claimed in an earlier-filed application. *See, e.g.*, *Miller*, 151 U.S. at 199. And, the patent applicant has the right to choose whether to claim the benefit of the filing date of the earlier application (resulting in an earlier priority date, but also an earlier expiration date), or to file the subsequent application in a separate family (resulting in later expiration date, but also a later priority date). *See Novopharm*, 104 F.3d at 1308.

Indeed, to take advantage of the post-GATT provisional procedure, the patentee ***must*** file its new application in an unrelated family.[19]

In either case, once filed, it is the ***PTO*** that determines which, if any, of the applicant's co-pending applications will issue first. *See, e.g.*, *Brigham*, 761 F. Supp. 2d at 225. And, even if the applicant could somehow control the issue dates of its various, copending applications, the district court's conclusion still permits only a single, twenty-year term of exclusivity for the applicant's first-patented invention, from the effective filing date to the expiry of its ***first-issued patent***. *In re Hubbell*, 709 F.3d at 1145. Any attempt to extend improperly the scope of that term of exclusivity through a ***second patent*** would appropriately be thwarted by the properly-applied double patenting doctrine. *See id.* In sum, what Natco refers to as "gamesmanship" is merely legitimate prosecution strategy that is entirely consistent with the principles underlying the obviousness-type double patenting doctrine.

IV. While Not Required for Summary Judgment, the District Court Correctly Held that the Issuance of the '483 Patent was Not the Result of Gilead Sciences' "Strategic Abuse" of the Patent System.

As Natco correctly notes, the issue on this appeal is a purely legal one—whether the later-issued, earlier-expiring '375 patent can serve as a reference

[19] 35 U.S.C. § 111(b)(7) provides that "[a] provisional application shall not be entitled to the right of priority of any other application under section 119 or 365(a) [of this title] or to the benefit of an earlier filing date in the United States under section 120, 121, or 365(c) [of this title]."

patent for determining whether the earlier-issued, later-expiring '483 patent is invalid for obviousness-type double patenting. Gilead's intent has no bearing on that legal analysis. (Blue Br. at 28-29.) Yet it was ***Natco***, not Gilead, that sought to improperly inject the irrelevant issue of Gilead's intent into the summary judgment proceedings by questioning the motives behind Gilead Sciences' prosecution strategy. (A476-77; A479; A481; A537; A541-42) For example, Natco asserted that, in contrast to *Brigham* and *Abbott Labs.*, "Gilead [Sciences] had complete control over the '375 and '483 patent terms because it had complete control over the filing dates," accusing Gilead Sciences of "repetitive filing of duplicative patent applications." (A481; *see also* Blue Br. at 9, 21-22.) Natco also seized on the separate prosecution of the '483 patent family to cast unfounded aspersions on how the patents were prosecuted, asserting that the Patent Office "did not catch the double patenting problem" before the '483 patent issued allegedly because Gilead Sciences did not disclose the application that led directly to the '375 patent. (A476; *see also* Blue Br. at 6.) Although not required for the grant of summary judgment, the district court explicitly rejected Natco's arguments as "ineffective," correctly finding that the issuance of the '483 patent was not the result of Gilead's "strategic abuse" of the patent system. (A7-8 (citing *Abbott Labs.*, 2011 WL 1897322, at *10).)

Natco has demonstrated no clear error in this conclusion. Indeed, Gilead Sciences' "control" over the filing dates of the applications that resulted in the '375 and '483 patents was no greater than that of any applicant for a patent, including the applicants in *Brigham* and *Abbott Labs.* Gilead Sciences appropriately used the CIP process to diligently disclose the continued development of its inventions of novel neuraminidase inhibitors. These applications were not "duplicative." Rather, each CIP application added information generated by continuing Gilead Sciences research—even adding additional inventors during the process. (A509.) It is not surprising that the '306 provisional application leading to the '483 patent is similar to applications in the '375 patent family. The inventors discovered the preferred compounds of the '483 patent in the course of the work disclosed in their '375 patent line of CIP applications. Natco apparently disputes Gilead Sciences' decision to seek protection for its preferred compounds through a separate line of applications. But Natco cites no rule or precedent suggesting that this was improper. On the contrary, in order to invoke the provisional procedure, which was specifically instituted by Congress to mitigate the impact of GATT on U.S. applicants' right to a patent term, a separate family of applications had to be filed. Diligent prosecution of both patent families happened to result in the issuance of the '483 patent claims before the claims that issued from the '375 patent line of CIP applications. This was not the result of any "gamesmanship" by Gilead

Sciences. Rather, it was the pace of Gilead Sciences' scientific work that dictated the filing date of the applications, and the pace of the PTO's examination of the applications that dictated their relative issue dates.

Natco's assertion that Gilead Sciences' non-disclosure of the '624 application during prosecution of the '483 patent was somehow improper (A476; *see also* Blue Br. at 17 n.7) is similarly unavailing, as the district court explicitly found. Indeed, as Natco admits, Gilead Sciences informed the '483 patent examiner of all prior-filed applications in the '375 patent family. (A7-8; A530.)[20] It is also undisputed that the '567 application that ***was*** disclosed to the PTO during prosecution of the '483 patent also included a disclosure that was identical to the disclosure in the '306 provisional. (A7-8; A530.) Thus, the undisputed facts demonstrate that the '483 patent examiner was aware that the '375 patent family of applications was pending, and included applications containing identical disclosure to the '306 provisional, with earlier effective filing dates than the application for the '483 patent. The examiner knew that the law governing patent term had changed and that any patent issuing from the '375 patent family, which claimed priority to earlier applications, would expire ***prior*** to the '483 patent. Yet, contrary to Natco's assertion that the '483 patent examiner "unquestionably" would have

[20] Unlike the other three applications in the '375 patent family, the '624 application was filed after the '306 provisional to which the '483 patent claims priority. (A508-11.)

conditioned allowance of the ’483 patent on a terminal disclaimer over the ’375 patent family, the ’483 patent examiner recognized that there was no obviousness-type double patenting before the issuance of a first patent to Gilead Sciences.

Under these circumstances, even if it were essential to the district court’s grant of summary judgment—which it was not—Natco has identified no clear error in the district court’s conclusion that the issuance of the ’483 patent was not the result of Gilead Sciences’ “strategic abuse” of the patent system. (A7-8.)

CONCLUSION

The judgment of the district court should be affirmed.

September 17, 2013

Respectfully submitted,

/s/ Patricia A. Carson

Leora Ben-Ami
Patricia A. Carson
Benjamin A. Lasky
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York NY 10022
(212) 446-4800

Counsel for Plaintiffs-Appellees

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

I certify that this brief complies with the type-volume limitation specified in Federal Rule of Appellate Procedure 32(a)(7)(B)(i). According to the word processing system used to prepare this document, the document contains 11,544 words.

/s/ Patricia A. Carson

CERTIFICATE OF SERVICE

On September 17, 2013, the undersigned caused the foregoing document to be filed electronically by using the Court's CM/ECF system. All parties are represented by registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Patricia A. Carson